

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: **Abelardo Silva et al.** CONF. NO.: **3064**
SERIAL NO.: **10/550,715** GROUP NO.: **1654**
FILING DATE: **August 16, 2006** EXAMINER: **Roy R. Teller**
TITLE: ***LONG ACTING BIOLOGICALLY ACTIVE CONJUGATES***

United States Patent and Trademark Office
Office of the Director
Mail Stop 1450
Alexandria, VA 22314

PETITION PURSUANT TO 37 C.F.R. § 1.181
FOR ENTRY OF THE RESPONSE TO OFFICE ACTION OF APRIL 28, 2010

Sir,

The applicants of the above-identified patent application hereby petition the Director to have the amendments proposed in the Response to Office Action of April 28, 2010 ("Response"), attached hereto as Exhibit A, considered by the Examiner and entered into the file. Three Exhibits, Exhibits A-C, accompany this Petition.

STATEMENTS OF FACT

1. On April 28, 2010, the Examiner issued a Final Office Action ("Office Action") requesting the cancellation of non-elected claims 48, 53, 81 and 136-145 and rejecting pending claims 18-28 and 30. Exhibit B. The claim rejections were as follows:

(a) claims 18, 19 and 23-26 were provisionally rejected on the ground of non-statutory double patenting over claims 1, 3-5, 9 and 10 of co-pending Application No. 10/478,811 (the '811 application). Exhibit B, pp. 2-3;

(b) claim 24 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to identify the amino acids represented by "Y1, Y2 Y3, etc." in the peptide recited therein. Exhibit B, p. 7;

(c) claims 18-28 and 30 were rejected under 35 U.S.C. § 112, first paragraph, as being non-enabled by the specification. The Examiner argued that "The specification, while being enabling for a composition and a method of inhibiting the activity of HIV, does not reasonably provide enablement for a composition and a method for inhibiting antiviral activity in vivo." Exhibit B, p. 4. The Examiner alleged that the specification does not satisfy the Wands factors (*In re Wands*, 858 F.2d 731 (Fed. Cir. 1993)) because it does "not show[] the effectiveness of the claimed C34 derivatives against viruses other than HIV." Exhibit B, p. 4.

2. On October 28, 2010, Applicants filed a timely response to the Examiner's arguments. In the Response, Applicants cancelled non-elected claims 48, 53, 81 and 136-145. Exhibit A, pp. 6 and 7. In addition, Applicants:

(a) requested that the non-statutory double patenting rejection be held in abeyance until the scope of patentable subject matter had been determined. Exhibit A, p. 7;

(b) amended claim 24 to include the definitions of Y1-Y14. Exhibit A, pp. 3-5 and 7; and

(c) contested the Examiner's enablement rejection but, nevertheless, amended claims 18-28 and 30 to address his concerns. That is, Applicants narrowed the claims to a complex and method of inhibiting the activity of HIV. Exhibit A, pp. 2-8.

3. Applicants did not, and do not now, acquiesce to the enablement rejection, for the reasons of record. Rather, Applicants intend to pursue the claims directed to antiviral activity in another application.

4. Applicants' Response does not contain new matter, and does not include either an affidavit or other evidence.

5. Applicants' amendments to the claims are strictly limited to the Examiner's suggestions and, thus, narrow the issues for appeal as required by 37 C.F.R. § 1.116(b).

6. On December 9, 2010, the Examiner issued an Advisory Action, refusing to enter Applicants' Response. Exhibit C.

7. According to the Examiner, Applicants' amendments to the claims "raise new issues that would require further consideration and/or search." Exhibit C, p. 2.

ARGUMENT

The Examiner has erred procedurally in refusing to enter Applicants' Response, and substantively in rejecting the claims under 35 U.S.C. § 112, first paragraph, as being based on a non-enabling disclosure.

On April 28, 2010, the Examiner issued a final Office Action in which he acknowledged that the specification enables "a composition and method of inhibiting the activity of HIV." Exhibit B, p. 4. However, the Examiner argued that the specification does not enable a composition and method for inhibiting antiviral activity *in vivo*. *Id.* In response, Applicants amended claim 18, the sole independent claim in the application, by substituting the phrase "possesses antiviral activity" with "inhibits HIV."

Amendments filed after a final rejection may be entered when they narrow the issues for appeal. 37 C.F.R. § 1.116(b)(1) states that "[a]n amendment may be made canceling claims or complying with any requirement of form expressly set forth in a previous office action." 37 C.F.R. § 1.116(b)(2) states that "[a]n amendment presenting rejected claims in better form for consideration on appeal may be admitted." Or, as stated in M.P.E.P. § 714.13(II):

An amendment at any time after final rejection, but before an appeal brief is filed, may be entered upon or after filing an appeal brief provided that the total effect of the amendment is to (A) remove issues for appeal, and/or (B) adopt the examiner's suggestions.

The proposed claim amendments in Applicants' Response comply with, and are strictly limited to, the aforementioned regulations and criteria. That is, the proposed claim amendments

adopt the examiner's suggestion for overcoming the enablement rejection and therefore, manifestly, narrow the issues for appeal. 37 C.F.R. § 1.116.

In addition, the Examiner has failed to provide any reasons for not entering the Response. Although the Examiner checked Box 3(a) on page two of the Advisory Action; the checked statement simply reads: "The[] [proposed amendments] raise new issues that would require further consideration and/or search (see NOTE below)." [Underlining added]. Exhibit C, p. 2. The reference to a NOTE indicates that an explanation of what needs to be considered and/or searched will follow. However, the Examiner's Note merely repeats the statement in Box 3(a) and, thus, fails to set forth any reasoning as to why the proposed amendments raise new issues.

Applicants only presume that the need for "further consideration and/or search" refers to the Examiner's stated concern with the phrase "inhibiting antiviral activity," in the enablement rejection. To that end, since the Examiner admitted, in the final Office Action, that the specification enables a composition and method of inhibiting HIV, it reasonably follows that he has already considered, and/or searched the anti-HIV activity of the claimed complexes. Accordingly, Applicants do not understand what additional consideration and/or search is required. Applicants respectfully submit that the Examiner's refusal to enter the proposed amendments is inconsistent with his own rejection and, thus, is untenable.

In view of the foregoing, Applicants respectfully request that the Director grant the present petition and direct the Examiner to enter the amendments in the Response to the final rejection filed on April 28, 2010.

CONCLUSION

The Applicants' Response cancels the withdrawn claims, and amends the remaining claims in the manner suggested by the Examiner. Thus, the Response narrows the issues for appeal and is in compliance with 37 C.F.R. § 1.116. Moreover, the amendments restrict the claims to the subject matter that the Examiner admits is allowable. The Examiner has provided no reasoning as to why entry of these amendments requires further search or consideration. Accordingly, Applicants respectfully request that the Director grant the instant petition and that the Response submitted on October 28, 2010 be entered into the file.

The Commissioner is hereby authorized to charge any fees that may be necessary to Attorney's Deposit Account No. 50-2283.

Date: March 25, 2011

Respectfully submitted,

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